4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0754. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

--OMB Control Number 0910-0754--Extension

This final Guidance for Industry and FDA staff entitled "Dear Health Care Provider Letters: Improving Communication of Important Safety Information" offers specific guidance to industry and FDA staff on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising.

This guidance gives specific instruction on what should and should not be included in DHCP letters. To date, some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information and have been unable to communicate it to patients because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes advice on consulting with FDA to develop a DHCP letter, when to send a letter, what type of letter to send, and conducting an assessment of the letter's impact.

Based on a review of FDA's Document Archiving, Reporting and Regulatory Tracking System for 2012 to 2015, we identified DHCP letters that were sent and the identity of each sponsor sending

out a DHCP letter for each year. We estimate that we will receive approximately 25 DHCP Letters annually from approximately 18 application holders. FDA professionals familiar with DHCP letters and with the recommendations in the guidance estimate that it should take an application holder approximately 100 hours to prepare and send DHCP letters in accordance with the guidance.

In the Federal Register of March 10, 2016 (81 FR 12734), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

FDA estimates the annual reporting burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Annual Average	18	1.4	25	100 hours	2,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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